



PATENT  
ATTORNEY DOCKET NO. JHU1530-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Worley, et al. Art Unit: 1646  
Application No.: 09/245,277 Examiner: Chernyshev, O.  
Filed: February 5, 1999 Conf. No.: 4724  
Title: IMMEDIATE EARLY GENES AND METHODS OF USE THEREFOR

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.132**

Madam:

I, Paul P. Worley, declare and state that:

1. I am a co-inventor of the subject matter described and claimed in the U.S. Patent Application Serial No. 09/245,277, filed on February 5, 1999 entitled, "Immediate Early Genes and Methods of Use Therefor", which claims priority to U.S. Patent Application Serial No. 60/074,518, filed February 12, 1998, and to U.S. Application Serial No. 60/074,135, filed February 9, 1998.

2. I am familiar with the prosecution history of U.S. Patent Application Serial No. 09/245,277.

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, August 15, 2005, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Karin Harden (Name of Person Mailing Paper)	
Karin Harden (Signature)	8-15-05 (Date)

3. I understand that the Examiner rejected claims 65-68 and 70-72 under 35 U.S.C. 101 as allegedly having no apparent or disclosed specific and substantial credible utility.

4. The protein of clone L-100 is associated with apoptosis.

5. When neurons in the brain are sufficiently stimulated to produce the protein of L-100 by a seizure, and the neurons subsequently die, either due to its putative apoptotic action or other cause, the protein should be detectable in the cerebrospinal fluid (CSF).

6. CSF is easily obtained from a subject by a physician by means of a spinal tap.

7. The protein sequence of L-100 is identical to axin 1 up-regulated 1, which has been named Axud1 (see Collins, PNAS, 2002, vol. 99, no. 26, 16899-16903).

8. Axud1 is identical to Mus musculus taip-3 mRNA for TGF- $\beta$  induced apoptosis protein 3, which has been named taip-3 (see Salahshor, et al., J. Clin. Pathol., 2005, 58, 225-236).

9. Thus, the protein sequence of L-100, or SEQ ID NO: 27, is associated with apoptosis.

In re Application of:

Worley et al.

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10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

8/12/2005  
Date

Paul Worley (S.P.)  
Dr. Paul P. Worley